## SUMMARY OF THE REGULATORY COORDINATION COMMITTEE MEETING OCTOBER 10, 2000

The Regulatory Coordination Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met by teleconference on Tuesday, October 10, 2000, at 12 p.m. Eastern Daylight Time (EDT). The meeting was led by its chair, Dr. Carl Kircher of the Florida Department of Health. A list of action items is given in Attachment A. A list of participants is given in Attachment B. The purposes of the meeting were to approve committee minutes from the Sixth NELAC Annual Meeting (NELAC 6), to review the April 2000 U.S. Environmental Protection Agency (EPA) Regulatory Agenda, to review a proposed revision of the model laboratory certification rules, and to discuss proposed changes to the NELAC Standard defining NELAC Scope of Accreditation and Proficiency Testing (PT) Fields of Testing by "matrix-method-analyte."

#### INTRODUCTION

Dr. Kircher called the meeting to order with a review of the agenda and study materials that had been distributed electronically prior to the meeting. Dr. Kircher briefly described and then facilitated discussion of the study materials as noted below.

#### APPROVAL OF MINUTES FROM NELAC 6

Dr. Kircher referred participants to the committee's June 27, 2000, meeting minutes. Although they met with approval from teleconference participants, formal approval of the minutes was deferred since there was not a quorum of voting members in attendance.

#### REVIEW OF EPA REGULATORY AGENDA

Dr. Kircher referred participants to his review of the April 2000 Regulatory Agenda, also distributed as an e-mail attachment prior to the meeting. The Regulatory Agenda will be presented to the Conference at the upcoming Sixth NELAC Interim Meeting (NELAC 6i). Dr. Kircher made the observation that EPA has consistently pushed back deadlines and questioned how useful it is for the Regulatory Coordination Committee to continue to review the agenda every six months. In response, a committee member expressed the opinion that the committee should continue to review the agenda every six months with particular attention to completed items and new items.

## REVIEW OF DOCUMENTS TO BE POSTED ON THE NELAC WEBSITE

Participants then turned their attention to the proposed model laboratory certification rules distributed prior to the meeting as an e-mail attachment. Dr. Kircher noted that the revision contains additional blanks for states to include their own regulatory criteria. The addition of state supplemental criteria has a two-fold purpose. It clarifies and summarizes for the Conference the great decision-making responsibility that has been entrusted to the primary accrediting authority. It also admonishes primary accrediting authorities that if they choose to exercise such decision-

making authority then their criteria should be documented in their administrative code. Dr. Kircher briefly reviewed the document as follows:

- Certification Criteria A space for state supplemental criteria regarding additional analytes and methods that are not required under any EPA programs that are part of NELAC has been provided. In discussion of certification criteria, it was noted that the EPA document number for the 2000 NELAC Standard is not yet available. Therefore, the model administrative code incorporates the latest approved NELAC Standard, dated July 1999. A committee member commented on potential delays in passing an administrative rule resulting from delays in the availability of the latest NELAC Standard.
- Certification Requirements This section covers the accreditation process. Spaces for state supplemental criteria, such as any statements about laboratory facilities in noncontiguous premises or mobile laboratory facilities requiring separate accreditation, and state Scope of Accreditation, have been provided.
- Certification of Out-of-State Laboratories A committee member noted that the level of information required for applications for secondary accreditation varies from state to state. Some states have a second application just for secondary accreditation while others require completion of the primary application. When laboratories must complete a primary application for secondary accreditation, there is no time-saving advantage. It was suggested that there should be some mechanism to streamline the process and that the NELAP National Database may do so. It was also suggested that having to submit copies of PT test results, Quality Assurance (QA) Manuals, and on-site assessment reports to a secondary accrediting authority when the primary accrediting authority has already reviewed these documents calls into question the review of the primary accrediting authority. The issue was tabled for further discussion at NELAC 6i.
- Proficiency Testing (PT) Requirements Spaces for state supplemental PT requirements, such as a predefined calendar schedule, and state supplemental PT criteria, such as statements about revocation or suspension of certification based on passing or failing PT samples, have been provided. There was some committee discussion of whether a laboratory can choose its PT provider or the provider will be stipulated by the accrediting authority.
- C On-site Laboratory Assessments A space for state supplemental requirements, such as statements about on-site laboratory assessments following a change in laboratory ownership or location or allowances and criteria for adding accreditation without an on-site assessment, has been provided.
- Renewal of Annual Certification The July 1 expiration date included in this section is based on the assumption of a July 1-June 30 state fiscal year. In committee discussion of the section, it was suggested that the space for expiration date could be left as a blank for states to complete with their pertinent information. The committee tabled the suggestion for further discussion at NELAC 6i.
- C Display of Certificate There were no comments on this section.

- Contractual Agreements, Records, and Reports In committee discussion of this section, it was suggested that a reference to subcontracting laboratories may be redundant with the NELAC Standards adopted by reference into the rule. The committee tabled this issue for further discussion at NELAC 6i.
- C Denial or Revocation of Certification In discussion of reciprocity issues involved with this section, a committee member asked whether primary accrediting authorities are required to notify secondary accrediting authorities of the revocation of a laboratory's certification. It was suggested that the comment should be addressed to the NELAC Accrediting Authority Committee. The committee tabled the issue for further discussion at NELAC 6i.

#### PROPOSED CHANGES TO NELAC STANDARD

The last electronically distributed document that participants reviewed constituted proposed changes to the NELAC Standard consistent with a redefined Scope of Accreditation. Dr. Kircher referenced a joint meeting of the NELAC Regulatory Coordination, Program Policy and Structure, Proficiency Testing, and Accrediting Authority Committees held at NELAC 6 to address consistency issues between the NELAC Scope of Accreditation and the PT Fields of Testing. Participants in an informal straw poll conducted at the joint meeting favored the "matrix-method-analyte" definition. In discussion of the proposed changes to the NELAC Standards, a convenient grouping for matrices for the PT Fields of Testing was suggested. Dr. Kircher suggested the following four manageable matrix groups:

- C Drinking Water
- C Other Aqueous Liquids/Saline Estuary
- C Air
- C Biological Tissues/Nonaqueous Liquids/Soils and Sediments/Chemical Waste

### **OLD BUSINESS**

Dr. Kircher noted that model administrative rules for several states have been posted on the NELAC Website.

### **NEW BUSINESS/CONCLUSION**

Dr. Kircher asked for presentation of any new business, and none was presented for consideration. He then made brief comments as the committee's chair. He noted that the potential exists at the next NELAC annual meeting for the Conference to make major changes to the NELAC Standard as follows:

- C to define Scope of Accreditation consistent with "matrix-method-analyte"
- C to redefine PT Fields of Testing consistent with "matrix-method-analyte"
- to incorporate ISO 17025 into Chapter 5
- C to vote on a Field Activities Standard

Dr. Kircher also asked for a volunteer or volunteers to deliver the documents discussed in the teleconference to their respective standing committees. It was suggested that Ms. Ilona Taunton or Mr. Eddie Clemons might deliver the documents. The allotted teleconference time having expired, the committee meeting was adjourned at 1:30 p.m. EDT.

# ACTION ITEMS REGULATORY COORDINATION COMMITTEE TELECONFERENCE OCTOBER 10, 2000

Item No.	Action	Date to be Completed
1.	Committee will consider points raised in 10/10/00 teleconference as issues for discussion at NELAC 6i.	NELAC 6i
2.	Ilona Taunton and Eddie Clemons will deliver documents discussed in 10/10/00 teleconference to their respective standing committees before Dr. Kircher's arrival at NELAC 6i.	NELAC 6i

# PARTICIPANTS REGULATORY COORDINATION COMMITTEE TELECONFERENCE OCTOBER 10, 2000

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